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Our Case No. 10000/232
Client Reference No. PA-5216-RFB-CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Boris Reydel et al.

Serial No.: 10/692,310

Filing Date: October 22, 2003

For: Introducer Apparatus With Eversible
Sleeve

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) Examiner: C. Witczak

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) Group Art Unit No.: 3767
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop: Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
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Dear Sir:

In response to the final Office Action dated February 27, 2009, Applicant submits this Appeal Brief in support of the appeal of the rejection of claims 1-49. Applicant's claims have been rejected twice, and thus Applicant is entitled to the present appeal. 37 CFR § 41.31(a). It is respectfully submitted that the rejection of claims 1-49 should be reversed for the following reasons.

I. Real Party in Interest

The real party in interest in the present appeal is Wilson-Cook Medical, Inc., the assignee of the entire right, title and interest in the application.

II. Related Appeals and Interferences

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned or Wilson-Cook Medical, Inc., "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

III. Status of Claims

Claims 1-49 are currently pending and have been rejected.

The rejections of claims 1-49 are being appealed in this appeal.

IV. Status of Amendments

All claim amendments have been considered by the Examiner.

V. Summary of Claimed Subject Matter

Independent claims 1, 23, 40 and 49 are each directed to an introducer apparatus 10 comprising a flexible introducer member 12 adapted to be introduced into the patient through an endoscope 78. (¶ [0059]; Figure 6). The introducer apparatus 10 further comprises a flexible sleeve 13 having a first body portion 106 and a second body portion 107. (¶ [0048]; Figure 4). The first body portion 106 is attached to the introducer member 12. (¶ [0048]; Figure 4). The second body portion 107 is moveable in response to movement of a second member 15 sized for introduction through the introducer member 12. (¶ [0051]; Figure 4). These claims further require that the second body portion 107 of the sleeve 13 to be disposed within and eversible from a passageway 22 of the second member 15 such that the second member passageway 22 is substantially unobstructed upon full deployment of the second body portion 107 there from. (¶¶ [0051]-[0052]).

Independent claim 41 is similar to the above discussed claims, but calls for a means for fixing a part of the sleeve 13 at a location external to and separate from an outside surface of the elongated member 15. (¶ [0048]). In the embodiment shown in Figure 4, the means is the introducer member 12. The claim further requires that a substantial part of the flexible sleeve 13 be movably located within an interior portion 22 of the elongated member 15. (¶ [0051]; Figure 4). Independent claim 48 is directed to method of reducing frictional effects when introducing an elongated member 15 and likewise requires a flexible sleeve 13 with a substantial length of the sleeve disposed in and eversible from an internal passageway 22 of the elongated member 15. (¶ [0051]; Figure 4).

The elements of independent claims 1, 23, 40, 41, 48 and 49 are recited below with citations to the preferred embodiments described in the specification.

1. An introducer apparatus for providing a reduced-friction pathway through an internal bodily passage of a patient, comprising:

a flexible introducer member (12) having a distal end and a proximal end, the introducer member (12) being adapted to be introduced into the patient through an endoscope (78) (Figures 4 and 6; ¶¶ [0048] and [0059]);

a sleeve (13) comprising a flexible material and which includes a first end (25), a second end (64), a first body portion (106), and a second body portion (107), the first body portion (106) being attached to the introducer member (12), the second body portion (107), which includes the second end (64), being moveable in response to movement of a second member (15) sized for introduction through the introducer member (12) and through the internal bodily passage (Figure 4; ¶ [0048]);

whereby the second body portion (107), including the second end (64), is disposed within and is eversible from a passageway (22) of the second member (15) such that the second member passageway (22) is substantially unobstructed upon full deployment of the second member (15) (Figure 4; ¶¶ [0051] and [0052]); and

whereby the sleeve (13) provides a reduced-friction pathway for at least a portion of the second member (15) during advancement thereof through the internal bodily passage (¶ [0056]).

23. An introducer apparatus for providing a reduced-friction pathway through an internal bodily passage of a patient, comprising:

a flexible introducer member (12) having a distal end, a proximal end, and a passageway (20) extending therethrough, the introducer member (12) being adapted to be introduced into the patient through an endoscope (78) (Figures 4 and 6; ¶¶ [0048] and [0059]);

a second member (15) having a distal end and a proximal end, the second member (15) being slidably disposed within the passageway (20) of the introducer member (12) (Figure 4; ¶ [0048]);

a sleeve (13) comprising a flexible material and which includes a first body portion (106) having a first end (25), and a second body portion (107) having a second end (64), the first end (25) of the first body portion (106) being attached to the introducer member (12), the second end (64) and at least a portion of the second body portion (107) being removably disposed within the passageway (22) of the second member (15) (Figure 4; ¶ [0048]);

whereby the second body portion (107) is eversible from the passageway (22) of the second member (15) in response to movement of the second member (15) relative to the introducer member (12), such that the passageway (22) is substantially unobstructed by the sleeve (13) upon full deployment of the second member (15) (Figure 4; ¶¶ [0051] and [0052]);

whereby a distal end of the second member (15) is spaced distally apart from the second end of the sleeve (13) upon full deployment of the second member (15) (¶¶ [0052] and [0056]); and

whereby the sleeve (13) provides a reduced-friction pathway for at least a portion of the second member (15) during advancement thereof through the internal bodily passage (¶ [0056]).

40. An introducer apparatus for providing a reduced-friction pathway into an internal bodily passage of a patient, comprising:

a flexible introducer member (12) having a distal end and a proximal end, the introducer member (12) comprising an elongate tube adapted to be introduced into the patient through an endoscope (78) (Figures 4 and 6; ¶¶ [0048] and [0059]);

a sleeve (13) comprising a flexible material and which includes a first body portion (106) and a second body portion (107), the first body portion (106) being attached to the introducer member (12), the second body portion (107) being moveable in response to movement of a second member (15) through the introducer member (12) and into the internal bodily passage, the second member (15) comprising an elongate tube adapted to slide through an internal passageway (20) of the introducer member (12) (Figure 4; ¶ [0048]);

whereby the second body portion (107) is unattached to the second member (15) and is disposed within and eversible from a passageway (22) thereof, such that the second member passageway (22), upon full deployment of the second member (15), is unobstructed by the sleeve (Figure 4; ¶¶ [0051] and [0052]); and

whereby the sleeve (13) provides a reduced-friction pathway for at least a portion of the second member (15) during advancement of the second member (15) into the bodily passage (¶ [0056]).

41. An arrangement for locating an elongated member (15) within an internal bodily passage of a patient, wherein a substantial part (107) of a flexible sleeve (13) is removably disposed within an interior portion (22) of the elongated member (15), and wherein means (12 and 14) are provided for fixing another part (106) of the sleeve (13) at a location external to and separate from an outside surface of the elongated member (15) so that when the elongated member (15) is moved in a distal direction, a distal part of the elongated member (15) engages and completely unfurls the substantial part (107) of the sleeve (13) between the outside surface of the elongated member (15) and an inside surface of the internal bodily passage (Figure 4; ¶¶ [0048] and [0052]).

48. A method of reducing frictional effects when introducing an elongated member (15) having a passageway (22) into an internal bodily passage, the elongated member (15) comprising a flexible sleeve (13) with a substantial length (107) of the sleeve (13) disposed in an internal passageway (22) of the elongated member (15) and with a part (106) of the sleeve (13) fixed at a location (14) outside of and separate from the elongated member (15), so that when the elongated member (15) is moved in a distal direction, a distal part of the elongated member (15) engages the sleeve (13) and unfurls it between an outside surface of the elongated member (15) and the internal bodily passage, the sleeve (13) being adapted so as to not obstruct the internal passageway (22) of the elongated member (15) upon unfurling from within the internal passageway (22) of the elongated member (15) (Figure 4; ¶¶ [0048] and [0052]).

49. An introducer apparatus for providing a reduced-friction pathway into an internal bodily passage of a patient, comprising:

- a flexible introducer member (12) comprising an elongate tubular member having an outer surface, a distal end, a proximal end, and a passageway (20) extending therethrough, the introducer member (20) being adapted to be introduced into the patient through an endoscopic device (78) (Figures 4 and 6; ¶¶ [0048] and [0059]);

- a second member (15) comprising an elongate tubular member having a distal end, the second member (15) slidably disposed within the passageway (20) of the introducer member (12) (Figure 4; ¶ [0048]);

- a tubular sleeve (13) comprising a thin polymeric film and which includes a first body portion (106) and a second body portion (107), the first body portion (106) being attached about the outer surface of the introducer member (12) at a location (14) near the distal end of the introducer member (12), the second body portion (107) comprising a second end (64) that is removably disposed within the passageway (22) of the second member (15), the sleeve (13) being responsive to movement of the second member (15) as the distal end of the second member (15) advances relative to and beyond the distal end of the introducer member (12) (Figure 4; ¶ [0048]); and

- whereby the second end (64) of the second body portion (107) is completely eversible from the second member passageway (22), thereby providing a reduced-

friction pathway for at least a portion of the second member (15), as the distal end of the second member (15) is advanced into the internal bodily passage and distally beyond the second end (64) of the second body portion (107) of the sleeve (13) (Figure 4; ¶¶ [0051], [0052] and [0056]).

VI. Grounds of Rejection to be Reviewed on Appeal

- A. The Examiner has rejected claims 1, 2, 6-21, 23-38 and 41-49 as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,946,440 to Hall.
- B. The Examiner has rejected claims 1, 3-5, 22, 23, 39 and 40 as being unpatentable under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,389,089 to Bauer et al.

VI. Argument

- A. Claims 1, 2, 6-21, 23-38 and 41-49 are not obvious over Hall.

Applicant seeks review of the Examiner's rejection of claims 1, 2, 6-21, 23-38 and 41-49 as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,946,440 to Hall. The ultimate issue before the Board is whether all of the limitations of Applicant's claims are either disclosed by or obvious in view of Hall. Applicant respectfully submits that the Examiner has failed to establish that Applicant's claims are obvious in view of Hall, and therefore, the Examiner's rejection should be reversed.

Hall is directed to a catheter having a flexible membrane (90) that is fixedly connected between an outer tube (12) and an inner tube (16). However, and as clearly shown in Figure 3, no portion of the membrane (90) is disposed within a passageway of the inner tube (16). To the contrary, the membrane (90) is fixedly connected to an exterior surface of the inner tube (16). Thus, Hall fails to disclose a flexible sleeve that is disposed within and eversible from a passageway of a second/inner member such that the passageway of the second/inner member is unobstructed upon full deployment as required by each of independent claims 1, 23, 41, 48 and 49.

Nevertheless, the Examiner has asserted that it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Hall to attach the second end of the flexible member to the inside of the second member “because Applicant has not disclosed that attaching the second end of the flexible member to the inside of the second member provides an advantage, is used for a particular purpose, or solves a stated problem.” (Office Action dated February 27, 2009, ¶ 1). Applicant respectfully disagrees.

First, there is no requirement that Applicant anticipate every difference between the invention and every prior art reference that an Examiner might conceivably rely upon during prosecution of the application, and then include in the application an explanation of any advantages the invention may provide over those differences. More specifically, there is no requirement that a patent application include speculation on the rejections an Examiner might assert and the prior art that the Examiner might rely upon. As a consequence, the Examiner cannot rely upon the absence of such speculation as demonstrating that the differences between the invention and a particular prior art reference (selected by the Examiner during prosecution) provide no advantages or is otherwise unimportant.

In any event, it must be pointed out that the specification for the present application provides a description of certain prior art and an explanation of at least some advantages of the invention over this art. For example, the Background of the Invention for the present application describes a urethral catheter disclosed in U.S. Patent No. 5,779,670 to Bidwell having a latex sleeve that is fixedly connected to the inside of the catheter by a sliding retention sled and to the outside of the catheter by a slidable collar. The specification explains that the attachment of the sleeve to the inside of the Bidwell catheter, although suitable for use in traversing the urethra, was not suitable for other procedures and had several disadvantages that were overcome by the present invention. In particular, the specification explains that certain procedures may not be completed if the sleeve remains connected to the inside of the catheter. The specification further explains that “the continued presence of the sleeve over the catheter would block critical side holes” of a feeding tube or decompression catheter (p. 2 of the present application). This latter advantage is particularly relevant to Hall, which

discloses a sleeve that is fixedly attached to the inner member in such a way that any side holes in the inner member (even though no side holes are disclosed or suggested) would be blocked by the sleeve. Thus, the specification for the present application describes advantages of the invention over specific features of the prior art, including the features disclosed in Hall that the Examiner has asserted would be obvious to modify.

Second, Hall discloses an arrangement wherein the sleeve is connected to the outside of the inner member. This arrangement has several disadvantages that are overcome by the present invention. One such disadvantage is that a portion of the sleeve is disposed between the inner and outer catheters, which results in an increase in the overall diameter of the combined devices. In contrast, the present invention utilizes a sleeve that is disposed within, and is eversible from, the inner catheter, which minimizes the overall diameter of the inner and outer members.

Accordingly, and for at least the reasons discussed above, independent claims 1, 23, 41, 48 and 49 are patentable over Hall. Claims 2 and 6-21 are each dependent on claim 1, claims 24-38 are each dependent on claim 23, and claims 42-47 are each dependent on claim 41. These dependent claims are therefore likewise patentable for at least the same reasons that independent claims 1, 23 and 41 have been demonstrated above to be patentable. Further discussion of these dependent claims is therefore unnecessary.

B. Claims 1, 3-5, 22, 23, 39 and 40 are not obvious over Bauer.

Applicant seeks review of the Examiner's rejection of claims 1, 3-5, 22, 23, 39 and 40 as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,389,089 to Bauer et al. The ultimate issue before the Board is whether all of the limitations of Applicant's claims are either disclosed by or obvious in view of Bauer. Applicant respectfully submits that the Examiner has failed to establish that Applicant's claims are obvious in view of Bauer, and therefore, the Examiner's rejection should be reversed.

Bauer is similar to Hall and likewise fails to disclose or suggest a flexible sleeve that is eversible from a passageway of a second/inner member. As best seen in Figures 3 and 4 of Bauer, the sleeve (45) is fixedly connected to the outside of the inner

member (43). Thus, Bauer likewise fails to disclose a flexible sleeve that is disposed within and eversible from a passageway of a second/inner member such that the passageway of the second/inner member is unobstructed upon full deployment as required by each of independent claims 1, 23 and 40.

Nevertheless, the Examiner has asserted that it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Bauer to attach the second end of the flexible member to the inside of the second member "because Applicant has not disclosed that attaching the second end of the flexible member to the inside of the second member provides an advantage, is used for a particular purpose, or solves a stated problem." (Office Action dated February 27, 2009, ¶ 2). Applicant respectfully disagrees.

First, and as noted above in connection with the discussion of the rejection under Hall, there is no requirement that Applicant anticipate every difference between the invention and every prior art reference that an Examiner might conceivably rely upon during prosecution of the application, and then include in the application an explanation of any advantages the invention may provide over those differences. In any event, and as demonstrated above, the specification for the present application describes advantages of the invention over specific features of the prior art, including the features disclosed in Bauer that the Examiner has asserted would be obvious to modify.

Second, Bauer, like Hall, discloses an arrangement wherein the sleeve is connected to the outside of the inner member. This arrangement has several disadvantages that are overcome by the present invention. One such disadvantage is that a portion of the sleeve is disposed between the inner and outer catheters, which results in an increase in the overall diameter of the combined devices. In contrast, the present invention utilizes a sleeve that is disposed within, and is eversible from, the inner catheter, which minimizes the overall diameter of the inner and outer members.

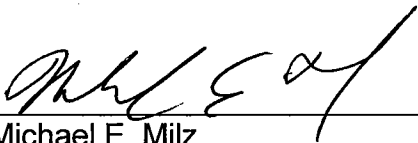
Accordingly, and for at least the reasons discussed above, independent claims 1, 23 and 40 are patentable over Bauer. Claims 3-5 and 22 are each dependent on claim 1, and claim 39 is dependent on claim 23. These dependent claims are therefore likewise patentable for at least the same reasons that independent claims 1 and 23

have been demonstrated above to be patentable. Further discussion of these dependent claims is therefore unnecessary.

VIII. Conclusion

Applicant respectfully submits that claims 1-49 are allowable over the prior art of record. As argued above, Applicant submits that the prior art of record does not disclose all of the limitations of Applicant's claims, and there would have been no apparent reason to modify the prior art of record in the manner that the Examiner has proposed in order to achieve the claimed inventions. Accordingly, Applicant requests that the Examiner's rejections of claims 1-49 be reversed and Applicant's application be allowed as presented.

Respectfully submitted,



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Claims Appendix

1. (Previously presented) An introducer apparatus for providing a reduced-friction pathway through an internal bodily passage of a patient, comprising:

a flexible introducer member having a distal end and a proximal end, the introducer member being adapted to be introduced into the patient through an endoscope;

a sleeve comprising a flexible material and which includes a first end, a second end, a first body portion, and a second body portion, the first body portion being attached to the introducer member, the second body portion, which includes the second end, being moveable in response to movement of a second member sized for introduction through the introducer member and through the internal bodily passage;

whereby the second body portion, including the second end, is disposed within and is eversible from a passageway of the second member such that the second member passageway is substantially unobstructed upon full deployment of the second member; and

whereby the sleeve provides a reduced-friction pathway for at least a portion of the second member during advancement thereof through the internal bodily passage.

2. (Original) The apparatus of claim 1, wherein the sleeve is an elongate tubular member having a passageway therethrough.

3. (Original) The apparatus of claim 2, wherein the sleeve comprises a thin polymeric film.

4. (Original) The apparatus of claim 3, wherein the sleeve comprises expanded polytetrafluoroethylene.

5. (Original) The apparatus of claim 3, wherein the sleeve comprises polyethylene.

6. (Original) The apparatus of claim 2, wherein the sleeve includes a plurality of apertures disposed thereabout.

7. (Original) The apparatus of claim 2, wherein the sleeve is configured to bias the second member in a predetermined direction in at least partial response to forward advancement of the second member within the sleeve.

8. (Original) The apparatus of claim 1, wherein the sleeve includes a circumferentially open portion extending at least partially along the length thereof.

9. (Previously presented) The apparatus of claim 8, wherein the sleeve is non-tubular in shape, such that it extends only partially around the circumference of the introducer member to which it is attached.

10. (Original) The apparatus of claim 1, wherein at least a portion of the second member is disposed within the introducer member, further wherein the second member comprises an elongate tube.

11. (Original) The apparatus of claim 1, wherein the introducer member comprises an elongate tube.

12. (Original) The apparatus of claim 11 wherein the internal passage is the patient's duodenum, and wherein the elongate tube has a first end, a second end, and a length that is sufficient to permit the first end to be located adjacent to the patient's duodenum while the second end is located outside of the patient.

13. (Original) The apparatus of claim 11, wherein the elongate tube includes at least a second passageway extending therethrough.

14. (Previously presented) The apparatus of claim 11, wherein the introducer member includes at least one longitudinal predetermined split line that permits, with manipulation by the operator, external access to the passageway of the introducer member to permit removal of the second member therefrom.

15. (Original) The apparatus of claim 1, wherein the introducer member comprises a plurality of longitudinal members that are configured to cooperate with the second member such that they are slidable relative to the second member to evert the sleeve from the passageway thereof.

16. (Original) The apparatus of claim 1, wherein the sleeve further includes a tether attached about the second end thereof, the tether sized such that the operator can reload the sleeve back into the second member from the proximal end of the introducer member.

17. (Original) The apparatus of claim 1, wherein the first end of the sleeve is permanently and circumferentially attached about an exterior surface of the introducer member.

18. (Original) The apparatus of claim 1, wherein the first end of the sleeve is releasably attached about the introducer member.

19. (Original) The apparatus of claim 1, wherein the second end of the sleeve is loadable into the passageway of the second member.

20. (Original) The apparatus of claim 1, wherein the sleeve further comprises a series of pleats, the pleats adapted to unfold longitudinally as the sleeve everts from the passageway of the inner member.

21. (Original) The apparatus of claim 1, wherein the introducer member includes a second passageway therein.

22. (Previously presented) The apparatus of claim 1 further comprising an endoscope, wherein the endoscope comprises a distal end, a proximal end, and a working channel, and further wherein at least a portion of the introducer member is disposed within the working channel of the endoscope.

23. (Previously presented) An introducer apparatus for providing a reduced-friction pathway through an internal bodily passage of a patient, comprising:

a flexible introducer member having a distal end, a proximal end, and a passageway extending therethrough, the introducer member being adapted to be introduced into the patient through an endoscope;

a second member having a distal end and a proximal end, the second member being slidably disposed within the passageway of the introducer member;

a sleeve comprising a flexible material and which includes a first body portion having a first end, and a second body portion having a second end, the first end of the first body portion being attached to the introducer member, the second end and at least a portion of the second body portion being removably disposed within the passageway of the second member;

whereby the second body portion is eversible from the passageway of the second member in response to movement of the second member relative to the introducer member, such that the passageway is substantially unobstructed by the sleeve upon full deployment of the second member;

whereby a distal end of the second member is spaced distally apart from the second end of the sleeve upon full deployment of the second member; and

whereby the sleeve provides a reduced-friction pathway for at least a portion of the second member during advancement thereof through the internal bodily passage.

24. (Original) The apparatus of claim 23, wherein the sleeve is at least 6 cm in length.

25. (Original) The apparatus of claim 23, wherein the sleeve is at least 20 cm in length and the introducer member comprises a feeding tube.

26. (Original) The apparatus of claim 23, wherein the introducer member and the second member each comprise elongate tubes.

27. (Original) The apparatus of claim 23, wherein the introducer member and second member each comprise catheters having a length of at least 150 cm.

28. (Original) The apparatus of claim 23, wherein the introducer member includes a second passageway, the second passageway being located relative to the point of attachment such that second passageway is not obstructed by a portion of the sleeve during use of the apparatus.

29. (Original) The apparatus of claim 23, wherein the distal end of the second member includes a friction-reducing mechanism located thereabout to facilitate passage of the sleeve thereover.

30. (Original) The apparatus of claim 23, wherein the second member is configured so as to be biased in a predetermined direction upon forward advancement within the sleeve.

31. (Original) The apparatus of claim 30, wherein the distal end of the second member is asymmetrical in shape.

32. (Original) The apparatus of claim 23, wherein the second member is adapted for delivery of a stent.

33. (Original) The apparatus of claim 23, wherein the apparatus is adapted for the introduction of a third member upon deployment of the second member.

34. (Original) The apparatus of claim 33, wherein the third member is preloaded within the passageway of the second member, the proximal end of the second member being configured to receive at least a portion of the third member.

35. (Original) The apparatus of claim 23, wherein the second member includes an expandable zone extending longitudinally therealong such that the passageway of the second member can be expanded in diameter.

36. (Original) The apparatus of claim 23, wherein the introducer member comprises a plurality of longitudinal attachment strips adapted for attaching the sleeve to the introducer member, one or more of the plurality of longitudinal attachment strips being slidably disposed within channels formed in the introducer member.

37. (Original) The apparatus of claim 23, wherein the second end of the sleeve is attached to the second member.

38. (Original) The apparatus of claim 23, wherein the second member includes a fluid reservoir portion adapted for the delivery of fluids therefrom.

39. (Original) The apparatus of claim 23, wherein the endoscope comprises a distal end, a proximal end, and a working channel, and further wherein at least a portion of the introducer member is disposed within the working channel of the endoscope.

40. (Previously presented) An introducer apparatus for providing a reduced-friction pathway into an internal bodily passage of a patient, comprising:

a flexible introducer member having a distal end and a proximal end, the introducer member comprising an elongate tube adapted to be introduced into the patient through an endoscope;

a sleeve comprising a flexible material and which includes a first body portion and a second body portion, the first body portion being attached to the introducer member, the second body portion being moveable in response to movement of a second member through the introducer member and into the internal bodily passage, the second member comprising an elongate tube adapted to slide through an internal passageway of the introducer member;

whereby the second body portion is unattached to the second member and is disposed within and eversible from a passageway thereof, such that the second member passageway, upon full deployment of the second member, is unobstructed by the sleeve; and

whereby the sleeve provides a reduced-friction pathway for at least a portion of the second member during advancement of the second member into the bodily passage.

41. (Previously presented) An arrangement for locating an elongated member within an internal bodily passage of a patient, wherein a substantial part of a flexible

sleeve is removably disposed within an interior portion of the elongated member, and wherein means are provided for fixing another part of the sleeve at a location external to and separate from an outside surface of the elongated member so that when the elongated member is moved in a distal direction, a distal part of the elongated member engages and completely unfurls the substantial part of the sleeve between the outside surface of the elongated member and an inside surface of the internal bodily passage.

42. (Original) An arrangement according to claim 41, wherein a sleeve fixation mechanism is provided for clamping the said another part of the sleeve relative to part of the anatomy of the patient whilst the said substantial part of the sleeve is unfurled.

43. (Original) An arrangement according to claim 42, wherein the said another part of the sleeve is affixed against movement relative to a distal end of an introducer member through which the elongated member is inserted and extended to the internal bodily passage.

44. (Original) An arrangement according to claim 43, wherein at least one of the introducer member and the flexible sleeve is made of splittable material that is adapted to be peeled back and removed so as to permit the elongated member only to remain in the internal bodily passage.

45. (Original) An arrangement according to claim 41, wherein means are provided for orienting the distal end of the elongated member during insertion into the internal bodily passage.

46. (Original) An arrangement according to claim 41, wherein the flexible sleeve is pleated when within the elongated member in order to minimize frictional effects.

47. (Original) An arrangement according to claim 43, wherein the elongated member and the introducer member each comprise elongated flexible tubes adapted to be introduced into the patient through an endoscopic device.

48. (Previously presented) A method of reducing frictional effects when introducing an elongated member having a passageway into an internal bodily passage, the elongated member comprising a flexible sleeve with a substantial length of the sleeve disposed in an internal passageway of the elongated member and with a part of the sleeve fixed at a location outside of and separate from the elongated member, so that when the elongated member is moved in a distal direction, a distal part of the elongated member engages the sleeve and unfurls it between an outside surface of the elongated member and the internal bodily passage, the sleeve being adapted so as to not obstruct the internal passageway of the elongated member upon unfurling from within the internal passageway of the elongated member.

49. (Previously presented) An introducer apparatus for providing a reduced-friction pathway into an internal bodily passage of a patient, comprising:

a flexible introducer member comprising an elongate tubular member having an outer surface, a distal end, a proximal end, and a passageway extending therethrough, the introducer member being adapted to be introduced into the patient through an endoscopic device;

a second member comprising an elongate tubular member having a distal end, the second member slidably disposed within the passageway of the introducer member;

a tubular sleeve comprising a thin polymeric film and which includes a first body portion and a second body portion, the first body portion being attached about the outer surface of the introducer member at a location near the distal end of the introducer member, the second body portion comprising a second end that is removably disposed within the passageway of the second member, the sleeve being responsive to movement of the second member as the distal end of the second member advances relative to and beyond the distal end of the introducer member; and

whereby the second end of the second body portion is completely eversible from the second member passageway, thereby providing a reduced-friction pathway for at least a portion of the second member, as the distal end of the second member is

advanced into the internal bodily passage and distally beyond the second end of the second body portion of the sleeve.